JUN 1 7 2005

510(k) Summary of Safety and Effectiveness: 21 CFR 807.92

Submitter's Name: Toshiba America Medical Systems, Inc.

PO Box 2068,2441 Michelle Drive Tustin, CA 92781-2068 Address:

Contact: Paul Biggins, Sr. Manager of Regulatory Affairs

Telephone No.: (714) 730-5000

Device Proprietary Name: SSA-530A, FAMIO

Common Name: Diagnostic Ultrasound System

Classification:

Regulatory Class: Π

Review Category: Tier II

Ultrasonic Pulsed Echo Imaging System – Product Code: 90-IYO

[Fed.Reg.No.:892.1560]

Diagnostic Ultrasonic Transducer – Product Code: 90-ITX

[Fed. Reg. No.: 892.1570]

Identification of Predicate Devices:

Toshiba America Medical Systems believes that this device is substantially equivalent to:

1) Toshiba NEMIO SSA-550A, Diagnostic Ultrasound; 510(k) control numbers are K010631 and K043078.

Device Description:

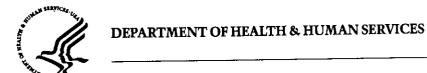
The FAMIO SSA-530A Diagnostic Ultrasound System is a mobile system. This system is a Track 3 device that employs a wide array of probes that include flat linear array and convex array with a frequency range of approximately 3.75MHz to 12MHz.

Intended Use:

The FAMIO SSA-530A is intended to be used for the following type of studies; fetal, abdominal, intraoperative, pediatric, small organs, neonatal cephalic, cardiac, transrectal, transvaginal, peripheral vascular and, musculo-skeletal (both conventional and superficial).

Safety Considerations:

This device is designed and manufactured in conjunction with the Quality System Regulation, IEC 60601-1 (applicable portions), IEC60601-2-37 (applicable portions), and the AIUM-NEMA UD2 Output Measurement Standard as applied to Track 3 Ultrasound systems and the AIUM-NEMA UD3 Output Display Standard.



Food and-Drug Administration 9200 Corporate Boulevard Rockville MD 20850

JUN 1 7 2005

Toshiba America Medical Systems, Inc. % Mr. Mark Job Responsible Third Party Official Regulatory Technology Services LLC 1394 25th Street NW BUFFALO MN 55313

Re: K051500

Trade Name: FAMIO Diagnostic Ultrasound System, Model SSA-530A

Regulation Number: 21 CFR 892.1560

Regulation Name: Ultrasonic pulsed echo imaging system

Regulation Number: 21 CFR 892.1570

Regulation Name: Diagnostic ultrasound transducer

Regulatory Class: II

Product Code: IYO and ITX

Dated: June 4, 2005 Received: June 7, 2005

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the FAMIO Diagnostic Ultrasound System, Model SSA-530A, as described in your premarket notification:

Transducer Model Number

PVQ-375A	
PVQ-641V	
PLQ-805A	
PLO-1203A	

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the <u>Federal Register</u>.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html

If you have any questions regarding the content of this letter, please contact Rodrigo C. Perez at (301) 594-1212.

Sincerely yours,

Mancy C Brogdon
Nancy C. Brogdon

Director, Division of Reproductive, Abdominal and Radiological Devices

Office of Device Evaluation

Center for Devices and Radiological Health

Enclosure(s)

System X Transducer Model SSA-530A	
510(k) Number(s)	

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Clinical Application	В	М	P W D	C W D	Color Dopple f	Amplit ude Dopple r	Color Velocity Imaging	Combined (Specify)	Tissue Harmonic Imaging*
Ophthalmic									
Fetal	N	N						N	N
Abdominal	N	N						N	N
Intraoperative (Specify)**	N	N					-	N	
Intraoperative Neurological									
Pediatric	N	N						N	N
Small Organ (Specify)***	N	N						N	
Neonatal Cephalic	N	N						N	
Adult Cephalic									
Cardiac	N	N						N	N
Transesophageal									
Transrectal	N	N						N	
Transvaginal	N	N						N	
Transurethral									
Intravascular									
Peripheral Vascular	N	N						N	
Laparoscopic									
Musculo-skeletal Superficial	N	N		-				N	
Musculo-skeletal Conventional	N	N						N	

N= new indication; P = Previously Cleared by FDA; E = Added under Appendix E (LTF)

Additional C	Comments: Combined Modes: B/M;
*	Tissue Harmonic Imaging does not use contrast agents
**	Abdominal
***	For example: thyroid, parathyroid, breast, scrotum and penis

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)11	
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	(Division Sign-Off)
	Division of Reproductive, Abdominal, And Radiological Devices (05/500) 5 (Olk) Number

Clinical Application Ophthalmic Fetal Abdominal	В	М					N/Indan	t i Inarati		
etal	- 1		P W D	C W D	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Tissue Harmonic Imaging*	<u></u>
Fetal	1		٦	-	 .		inaging		imaging	
\bdominal	N	N						N	N	
	N	N						N	· N	
traoperative (Specify)	1	-								
raoperative Neurological							-			
diatric	N	N						N	N	
nall Organ (Specify)										
onatal Cephalic										
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Clinical Application	В	М	P W D		Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Tissue Harmonic Imaging	
Ophthalmic	\dagger				· · · · · · · · · · · · · · · · · · ·					
Fetal .			-							
Abdominal	1								,	
Intraoperative (Specify)	1			\dashv		· · · · · · · · · · · · · · · · · · ·		 		
Intraoperative Neurological	+	<u> </u>								
Pediatric	+			_						
Small Organ (Specify)	1									
Neonatal Cephalic		\vdash						 		
Adult Cephalic	1		\neg							
Cardiac	+		\dashv							
Transesophageal	+	\vdash		\dashv						
Transrectal	N	N						N		
Transvaginal	N	N	\dashv					N		•
Transurethral	\top	┞─┤	\neg	\dashv						
Intravascular	+		-	-						
Peripheral Vascular		┝╼┥	\dashv	\dashv						
Laparoscopic	+-	\vdash	\dashv	\dashv						
Musculo-skeletal Superficial	$\dagger \dashv$		一	\dashv						
Musculo-skeletal	╅━┪	-	-	-						
Conventional										
N= new indication;	P =	Pre	vic	1115	v Cleare	d by FDA	E = Add	led under A	nnandiy I	Z (I TE)
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System ____ Transducer X

Ophthalmic Fetal Abdominal Intraoperative (Specify) Intraoperative Neurological Pediatric Small Organ (Specify) Neonatal Cephalic Adult Cephalic Cardiac Transesophageal Transvaginal Transvaginal Transvaginal Transurethral Intravascular Peripheral Vascular Laparoscopic Musculo-skeletal Superficial N= new indication; P = F Additional Comments: [PLEAS	'	P C W W	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Tissue Harmonic Imaging	
Fetal Abdominal Intraoperative (Specify) Intraoperative Neurological Pediatric Small Organ (Specify) Neonatal Cephalic Adult Cephalic Cardiac Transesophageal Transrectal Transvaginal Transvaginal Transurethral Intravascular Peripheral Vascular Laparoscopic Musculo-skeletal Superficial N=new indication; P = F Additional Comments:	N							
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Clinical Application	В	М	P W D		Color Doppler	Amplitude Doppler	Color Velocity	Combined (Specify)	Tissue Harmonic	
Ophthalmic		 					Imaging	<u> </u>	lmaging	
Fetal										1
Abdominal		 							······································	
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Pediatric	1	 							·	
Small Organ (Specify)	N	N		\dashv				N	····	
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aparoscopic	+	-`\	\dashv	+				N		
Ausculo-skeletal Superficial	N	N	\dashv							
Ausculo-skeletal	N	N	-	-				N		
Conventional		-						N		
N= new indication; Additional Comment								ed under A	appendix I	E (LTF)
										
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Clinical Application	В							f Operation	
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Fetal									
Abdominal	N	N						N	
Intraoperative (Specify)									
Intraoperative Neurological									·
Pediatric	N	N						N	
Small Organ (Specify)									
Neonatal Cephalic	N	N						N	
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Prescription Use (Per 21 CFR 801.109)

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510(k) Number

Clinical Application Ophthalmic	В	M		1						
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Fetal										
Abdominal	N	N						N		
Intraoperative (Specify)	N	N						N		
Intraoperative Neurological									·	
Pediatric	N	N						N		
Small Organ (Specify)										
Neonatal Cephalic										
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Small Organ (Specify) Neonatal Cephalic Adult Cephalic Cardiac NNN Transesophageal Transrectal Transvaginal Transurethral Intravascular Peripheral Vascular Laparoscopic Musculo-skeletal Musculo-skeletal							Mode o	f Operati	on	·
Ophthalmic Fetal N N N Abdominal N N N Intraoperative (Specify) Intraoperative Neurological Pediatric N N N Small Organ (Specify) Neonatal Cephalic Adult Cephalic Cardiac N N N Transesophageal Transrectal Transrectal Transvaginal Transurethral Intravascular Peripheral Vascular Laparoscopic Musculo-skeletal Musculo-skeletal Conventional	Clinical Application	В	М	w	W		Velocity		Harmonic	
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N= new indication; P = Previously Cleared by FDA; E = Added under Appendix E (LTF)										
Additional Comments: Combined Modes: B/M	Ausculo-skeletal Conventional N= new indication;							ed under A	ppendix E	(LTF)

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number